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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,514

Applicant(s)

SIMAS ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/1/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Detailed Action.

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "16" has been used to designate both the distal portion of the holder and what appears to be the cannula (see figure 3). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, *the removal of the adapter from the member and fitting of a collection store to the proximal portion of the member* as set forth in claim 11 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it is too long, it exceeds 150 words. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 11 objected to because of the following informalities: in lines 5-6, the recitation of a fluid path **form** said luer does not make sense and therefore the claim is confusing. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 & 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of each claim sets forth a "method of claim 5" however claim 5 is a device claim. Correction is required.

Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: in claims 10-12 (and presumably, as best can be understood, claims 13 & 14 are intended to be dependent from claim 10 and therefore also would include this indefinite limitation), the preamble sets forth a "method of transferring fluid from a syringe or patient to different dimensioned fluid

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collection stores.” However, no step of collection is recited. The claims appear to be more a method of connecting or attaching various parts of a device. For example, the language “fitting” and “connecting” respective structure in claims 10 & 11 as well as the language “forming” in claims 12-14 assert a method of attaching/connecting a device rather than transferring fluid through a device.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-6, 8-11, 13, & 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Sampson et al. (2004/0215106). Sampson et al. (hereafter Sampson) discloses a transfer needle apparatus comprising a shield 10 (i.e. cylindrical member) having a closed distal end 18, said end fitted with a luer 29 for with a tubular opening 27 (i.e. cannula) extending therefrom for communicating with a needle 56, and a proximal end 22 that is open. The distal end has a smaller diameter than the proximal end. The device further comprises a removable sleeve 30 (i.e. adapter) that is adapted to fit/mate with the shield. The adapter has a flange 38 (i.e. base) and a central opening, a cylindrical tube 32, wherein the tube has a smaller diameter than the shield. A shoulder

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is formed where the distal and proximal ends of the shield meet. The sleeve further does not have a contiguous circular wall, since a plurality of ribs 40 that extend out from the body and provide a fit with the inner contour of shield for cooperatively engagement of the shield and sleeve. The shield (i.e. member) has a flange 46 extending circumferentially about the open end, which will act upon the flange 38 (i.e. base) adapter. Sampson shows multiple fluid collection devices (i.e. fluid collection store) attached to the device, such as a medicine bottle and vacutainer tube.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 2, 7, & 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Sampson et al. (2004/0215106). Sampson et al. (hereafter Sampson) discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that a circumferential groove be formed along the inside surface of the proximal portion and protuberances forced externally at a section of said wall of the adapter, such that when the adapter is inserted the protuberances will mate with the groove to prevent the adapter from being inadvertently disengaged. At the time of the invention, it would have been an obvious design choice to modify the engagement mechanism that is the use of plurality of ribs that extend out from the body and provide a fit with the inner contour of shield for cooperatively engagement of the shield and sleeve, of Sampson by substituting a circumferential groove and protuberance to provide engagement, since they are equivalent connection means known in the art. Therefore, because these two connections were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to modify Sampson.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Brignola (4,296,786) & Jansen et al. (6,601,721) disclose known medical connectors in the art.

Velasquez (5,536,262) & Aneas (5,879,345) disclose similar medical connectors, however, the adapter is of a greater diameter than the cylindrical member.

Hopkins et al. (6,875,204) discloses an analogous device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 16th, 2005

Patricia M Bianco
Primary Examiner
Art Unit 3762


PATRICIA BIANCO
PRIMARY EXAMINER